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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/748,389	12/29/2003	Mineo Yamakawa	21058/0206773-US0	8159
75172 Client 21058 c/o DARBY & DARBY P.C. P.O. BOX 770 CHURCH STREET STATION NEW YORK, NY 10008-0770				
EXAMINER				
WRIGHT, PATRICIA KATHRYN				
ART UNIT		PAPER NUMBER		
1797				
MAIL DATE		DELIVERY MODE		
09/09/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/748,389

Applicant(s)

YAMAKAWA ET AL.

Examiner

P. Kathryn Wright

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 July 2008.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 10-22, 31-40 and 55-66 is/are pending in the application.
4a) Of the above claim(s) 55, 58-60 and 63 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1, 10-22, 31-40, 56-57, 61-62, and 64-66 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

Status of the Claims

1. This action is in response to papers filed May 20, 2008 and July 31, 2008 in which claims 1, 22, 57 and 62 were amended, claims 8-9, 23, 29-30 were canceled and claims 65-66 were added. The amendments have been thoroughly reviewed and entered. Any objection/ rejection not repeated herein have been withdrawn.

Applicant's arguments have been thoroughly reviewed but are deemed moot in view of the amendments, withdrawn rejections, and new grounds for rejection. New grounds for rejection, necessitated by the amendments, are discussed.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1, 10-22, 31-40, 56-57, 61-62, and 64-66 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 22 now recites "wherein the porous membrane is a sensor exhibiting sensing characteristics causing a change in at least one of an optical and electrical characteristic in response to exposure to a targeted fluid or reaction". It is not clear what Applicant means by the phrase "sensing characteristic". Nor does the specification clarify the matter. At page 7 of the Response filed on July 31, 2008, Applicant argues the polycarbonate film of Bohn is not a semiconductor material such as silicon that can be used for electronic and photovoltaic applications. It is not clear

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how the use of a semiconductor material such as silicon provides a "sensing characteristic".

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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7. Claims 1, 10-22, 31-40, 56-57, 61-62, and 64-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent Pub. No. 2003/0136679 to Bohn et al., (hereinafter "Bohn") in view of US Patent Pub No. 2003/0148524 to Zimmermann et al., (hereinafter "Zimmermann").

Regarding claims 1, 22, 29, 56, and 61, Bohn teaches a microfluidic device 20 comprising a source fluid flow channel 28 formed in lower substrate 24 and a target fluid flow channel 30 formed in the upper substrate 26. Note that the source fluid channel could be disposed in upper substrate and the target fluid could be disposed in the lower substrate and the device would function the same. The target fluid flow channel is in fluid communication with the source fluid flow channel at a cross-channel area. As shown in Fig. 1, the source fluid flow channel 28 crosses over the target fluid flow channel 30 in an "X fashion" at the cross-channel area (i.e., perpendicular, see paragraph [0039]; claim 21).

The Bohn device also includes a porous membrane 22 integral with the substrates 24, 26 (claim 18) and separating the source fluid flow channel from the target fluid flow channel in the cross-channel area. The porous membrane 22 is a sensor exhibiting sensing characteristics causing a change in an electrical characteristic in response to exposure to a targeted fluid or reaction. That is, Bohn teaches the interior surface 60 of each pore 42 may be coated with a coating 62 (see Fig. 3), so that molecules passing through the pore are likely to contact coating. For example, the pores 42 may be coated with a particular reagent causing a reaction. Bohn teaches the coating 62 may be electrically charged or metal (gold) which would cause a potential change in an optical and/or electrical characteristic of the porous membrane 20 (See paragraph [0028]). Note gold is a conductor that can be used for

electronics and photovoltaic applications. Thus, like the present invention, the porous membrane of Bohn is manufactured to produce a changed optical and/or electrical characteristic through the addition of a sensor layer (i.e., coating 62). It is noted that Applicant teaches the addition of a sensor layer as an alternative to use of a base silicon substrate material (e.g., PSi or PPSi), see paragraph [0039] of the specification.

Bohn also teaches a field-force/gradient mechanism 50 proximate the porous membrane (see Figs. 1, 4-5c). The field- force/gradient mechanism generates an electric field to produce a fluid movement of a fluid from the source fluid flow channel to the target fluid flow channel via the porous membrane located in the cross-channel area, see paragraphs [0027], [0031]-[0033], [0060]-[0064].

While Bohn does teach the use of a nanoporous membrane 22, preferably made of polycarbonate, Bohn does not specifically teach the membrane being made of a porous silicon membrane. However, Bohn states the membrane could be made of other material without departing the from the scope of the invention, see paragraph [0026].

Zimmermann teaches a microfluidic device including a measuring chamber divided into two compartments 11, 12 by a porous membrane 3. The membrane has pores 2 by way of which the compartments are connected (see Fig. 1 and paragraph [0026]). The microfluidic device of Zimmermann includes a field force/ gradient mechanism (electrodes 4, 5) proximate the porous membrane 3 configured to produce fluid movement from compartment 11 to the other compartment 12 or *vice versa*.

Zimmermann teaches the carrier member can be formed of a membrane comprising polycarbonate or silicon nitride (see paragraph [0028]). Note the claims recite the porous membrane "comprising" porous silicon membrane. "Comprising" is a

term of art used in claim language which means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim. Thus, porous silicon nitride membrane reads on the "porous silicon membrane".

Furthermore, like the membrane used in the instant invention, the thickness of the Zimmermann membrane is between the range of 0.5 to 30 microns, see paragraph [0028]. The system of Zimmermann also includes an optical detector in communication with data collection equipment that collects data pertaining to changes in the optical characteristic of the porous membrane (see paragraph [0029]).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time of the claimed invention substituted the membrane of Bohn with the porous silicon membranes of Zimmermann, since Bohn teaches that the membrane may be made of other material without departing from the scope of the invention (see paragraph [0026]) and since Zimmermann teaches the equivalence of a porous silicon membrane and polycarbonate membrane.

As to claims 10 and 31, Bohn teaches fluorescence spectroscopy and imaging (light source a detector) focused at the membrane 22 see paragraph [0060].

With respect to claims 11 and 32, Bohn also teaches the membrane 22 having a thickness 46 between 1 μm and 100 μm , within the claimed range of 0.01 and 50 micrometers (see paragraph [0026]).

Regarding claims 12 and 33 Bohn teaches the porous membrane 22 is capable of fractionating molecules base on size, molecular weight, charges, chemical affinity (see for example paragraphs [0060]-[0065].

As to claims 14, 16 and 37, Bohn teaches the substrates 24, 26 made of silicon or polydimethyl siloxane (PDMS), see paragraphs [0025], [0039].

Regarding claims 19-20 and 39-40, please note that a recitation with respect to the manner in which a claimed apparatus is intended to be employed, (i.e., disposed or reused) fails to differentiate the claimed apparatus from a prior art apparatus if the prior art apparatus teaches all the structural limitations of the claim. *Ex parte Masham*, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987).

As to claim 59 note that Bohn teaches array of multiple paths formed from a plurality of source and target fluid channels (see Fig. 9b and paragraphs [0023] and [0058]).

Regarding claims 65-66, Bohn does teach the porous membrane has a property of being a passive diffusion barrier (i.e., filter) between the source fluid flow channel and target fluid flow channel.

As discussed above, Bohn does teach the use of a nanoporous membrane 22 disposed between the upper and lower substrates 24, 26. Bohn does discuss the desirability of placing the nanoporous membrane between the upper and lower substrates without wrinkling or deforming the membrane and sufficiently holding the membrane in place for subsequent handling, but not so tightly as to permanently bond the membrane to the carrier (see paragraph [0042]).

Bohn do not teach the membrane being located in a hollow space formed by the first and second cavities or recessing in the upper and lower substrates. However, it would have been obvious to one ordinary skill in the art at the time of the claimed invention to form a first cavity and second cavity in the upper and lower substrate so that the membrane is located in a hollow space (recess) created by the first and

second cavities in the upper and lower substrate, since the hollow cavities in the upper and lower substrates would help hold the nanoporous membrane in place for subsequent handling and prevent wrinkling or deforming the membrane.

Terminal Disclaimer

8. The terminal disclaimer filed on May 20, 2008 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US Patent No. 6,606,543 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Double Patenting

9. The provisional rejection of claims 13-14 and 34-35 on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claims 38-39 and 41 of copending Application No.10/856,372 is held in abeyance until indication of allowance of the claims.

Response to Arguments

10. Applicant's arguments with respect to claims 1, 10-22, 31-40, 56, 61-62, 64-66 have been considered but are moot in view of the new ground(s) of rejection.

In response to Applicant argument that the polycarbonate film in Bohn's device in US Patent Pub. No. 2003/0136679 is not capable of "exhibiting sensing characteristics causing a change in at least one of an optical and electrical characteristic in response to exposure to a targeted fluid or reaction" as recited in independent claims 1 and 22 as polycarbonate is not a semiconductor material such as silicon that can be used for

electronics and photovoltaic applications. Applicant argues that to monitor the flow of the reagent molecules through the device, Bohn attaches fluorophores to the reagent molecules because polycarbonate on its own does not exhibit sensing characteristics causing a change in at least one of an optical and electrical characteristic in response to exposure to a targeted fluid or reaction.

The Examiner respectfully disagrees. As discussed above, the Bohn device includes a porous membrane 22 wherein the interior surface 60 of each pore 42 may be coated with a coating 62 (see Fig. 3), so that molecules passing through the pore are likely to contact coating. Furthermore, Bohn teaches the coating 62 may be electrically charged or metal (gold) which would cause a potential change in an optical and/or electrical characteristic of the porous membrane 20 (See paragraph [0028]). Gold is a conductor that can be used for electronics and photovoltaic applications, see for example US Patent No. 6,867,120. Thus, like the present invention, the porous membrane of Bohn is manufactured to produce a changed optical and/or electrical characteristic through the addition of a sensor layer (i.e., coating 62). Also note, that Applicant teaches the addition of a sensor layer as an alternative to use of a base silicon substrate material (e.g., PSi or PPSi), see paragraph [0039] of the specification. Thus, contrary to Applicant's assertion the polycarbonate film in Bohn's device is capable of exhibiting sensing characteristics causing a change in at least one of an optical and electrical characteristic in response to exposure to a targeted fluid or reaction since polycarbonate in Bohn includes semiconductor material (i.e., gold) that can be used for electronics and photovoltaic applications.

Conclusion

11. No claims are allowed.
12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

1. Any inquiry concerning this communication or earlier communications from the examiner should be directed to P. Kathryn Wright whose telephone number is (571)272-2374. The examiner can normally be reached on Monday thru Thursday, 9 AM to 6 PM, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

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Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

pkw

/Jill A. Warden/
Supervisory Patent Examiner, Art Unit 1797